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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,127

12/22/2003

Frank J. Bunick

MCP-5022

8480

27777

7590

02/27/2007

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

10/743,127

BUNICK ET AL.

Examiner

Art Unit

Susan T. Tran

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Dake et al. US 2003/0026872.

Dake discloses a composition comprising active agent, sweetening agent, and one or more flavoring agents suitable for reconstitution with a liquid, including syrup to form an oral liquid dosage form (abstract; paragraphs 0027-0036, 0110 and 0117; and claims). Flavoring agents include mixture of a variety of well-known forms such as encapsulated flavor agent (paragraphs 0118-0122; and claims).

Claims 1-3 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Buxton et al. US 6,428,808.

Buxton discloses a liquid oral dosage comprising one or more flavoring vehicles and a medicament (abstract; column 1, lines 44-65; column 5, lines 35-

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36; and column 6, lines 13-20). The liquid dosage can be in any pharmaceutical formulation such as solution, suspension, emulsion or syrup form (column 2, lines 45-55). Flavoring vehicle comprises an edible solid substrate in the form of a small wafer or thin sheet of water-dispersible or water-soluble non-toxic material, having a thickness of 0.5-2 mm (column 4, lines 33-65). Flavoring vehicle may be in particles form (column 5, lines 21-30). Buxton further discloses the flavoring vehicle is made of known material including starch, cellulose, and polysaccharides (column 4, lines 47-59).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. US 6,428,808, in view of Mathiowitz et al. US 4,861,627 or Porzio et al. WO 97/13416.

Buxton is relied upon for the reason stated above. However, Buxton does not explicitly teach the claimed encapsulated flavoring vehicle that has a controlled release property.

Mathiowitz teaches a method for the preparation of multilayer microcapsule comprising flavoring agent suitable for controlled release of the flavoring agent (abstract; column 1, lines 9-11; and column 3, lines 55-60).

Porzio teaches a process for preparing a double encapsulated controlled release microcapsule comprising flavoring agent (abstract; page 22; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Buxton using the microcapsules in view of the teachings of Mathiowitz and Porzio, because Mathiowitz and Porzio teach microencapsulating flavoring agent is well known in the art, and because Buxton teaches the use of flavoring powder or flavoring granules.

Regarding the film thickness, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable thickness that would fall within the claimed range, because Buxton teaches a film thickness of 0.5 mm, which is very close to the claimed range (about 0.25 mm), and because Buxton teaches a similar flavoring composition for the same purpose, namely, masking the bitter taste of active agent to obtain a useful pharmaceutical formulation for pediatric and geriatric.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ulrich et al., and Nelson et al. are cited as of interest for the teaching of palatable microcapsule compositions.

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**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN  
PRIMARY EXAMINER



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